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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,920	09/05/2003	Hassan Mostafavi	VM 03-006-US	8620
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EXAMINER				
LAURITZEN, AMANDA L				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/655,920

Applicant(s)

MOSTAFAVI, HASSAN

Examiner

Amanda Lauritzen

Art Unit

3737

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29, 31-51, 53-55 and 57-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29, 31-51, 53-55 and 57-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to communications filed 18 March 2011. Amendments to the claims do not introduce new matter. Objection to claim 53 has been withdrawn in view of the amendment(s).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive and/or are moot in view of new grounds of rejection.

Applicant has amended claim 1 to include a step of performing image subtraction using first and second images from a sequence of images. Examiner points to the cited Schweikard et al. (US 2004/0092815), in which a subtraction is performed on consecutive images in a series, as in [0044]. As the designations "first" and "second" are merely names to identify the images of the method being used in the subtraction process, the examiner holds that the consecutive images used in the subtraction in the method of Schweikard et al. are identifiable as first and second images in a series. Additionally, it is understood that the methods of Schweikard et al. accommodate uninterrupted image acquisition in which multiple composite images are formed by a process of image subtraction between subsequent images in real time. It is further held, by corollary, that each of the images in each of the sets of composite-subtractions are "first" and "second" with the first being the one that is temporally preceding the second in a consecutive image series.

As to the above-addressed amendments to claim 1, Takeo additionally teaches subtraction (composite) images and discloses using contrast values to determine threshold values, as in col.

1, lines 50-64 and col. 19, lines 11-28, in which a contrast value is used. The methods of Takeo are cited in combination with those of Kalend, and examiner holds this to render the amended method of claim 1 obvious by the same rationale presented above; namely-- it is posited that a subtraction (as disclosed in either reference to Takeo or Schweikard et al.) is performed on consecutive images in a series. As the designations "first" and "second" are merely names to identify the images of the method being used in the subtraction process, the examiner holds that the consecutive images used in the subtraction in the methods disclosed are identifiable as first and second images in a series. Additionally, it is understood that the methods accommodate uninterrupted image acquisition in which multiple composite images are formed by a process of image subtraction between subsequent images in real time. It is further held, by corollary, that each of the images in each of the sets of composite-subtractions are "first" and "second" with the first being the one that is temporally preceding the second in a consecutive image series.

As to applicant's remarks on p. 2 of the response, examiner does not concede that the method of claim 1 requires a single image device as asserted. Examiner maintains that the pre-therapy and therapy images of Schweikard et al. are first and second images in a temporal "sequence" (more than one consecutive image), regardless of the number of image acquisition units. The number of image acquisition units is not held to be a grounds for patentable distinction. Additionally, the method is not understood to require more than one session, regardless of whether the image(s) are designated pre-therapy or therapy. This simply designates whether the image was acquired before or during one (single) therapy session. For this reason, the pre- and therapy images are understood to be a part of the same session and therefore the

same sequence (as they have also been shown to create a temporal sequence of images of the same patient in a single session).

As to remarks p. 3, it has been contested that the beam direction data identified by the examiner in Schweikard et al. does not constitute treatment data. Examiner disagrees and maintains that beam direction data is data related to the therapy as therapy data is so broad as to encompass the treating beam intensity, direction, duration, etc. For these reasons, it is held that the Schweikard et al. reference includes treatment data.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Schweikard et al. (US 2004/0092815).

Schweikard et al. disclose method for gating a medical procedure, such as a radiation therapy procedure, in which a sequence of images is acquired prior to treatment for comparison with a series of images acquired during treatment to detect patient movement such that the position of the radiation beaming apparatus can be continuously adjusted to follow a moving target, as in the abstract, [0021], [0023], [0024], [0028]. A comparison is made between the pre-therapy and therapy images, including an image subtraction, with the resulting image being a composite image, [0044]. The direction of the radiation beaming apparatus is controlled based

on any detected movement of the target based on the comparison of the images. Gray level values are compared for each pixel, with accumulated differences assisting in image matching for detection of target movement and ultimately for a corresponding adjustment of the radiation beam, [0044], [0024], [0021].

In the method of Schweikard et al., a subtraction is performed on consecutive images in a series, as in [0044]. As the designations "first" and "second" are merely names to identify the images of the method being used in the subtraction process, the examiner holds that the consecutive images used in the subtraction in the method of Schweikard et al. are identifiable as first and second images in a series. Additionally, it is understood that the methods of Schweikard et al accommodate uninterrupted image acquisition in which multiple composite images are formed by a process of image subtraction between subsequent images in real time. It is further held, by corollary, that each of the images in each of the sets of composite-subtractions are "first" and "second" with the first being the one that is temporally preceding the second in a consecutive image series.

The pre-therapy and therapy images of Schweikard et al. are first and second images in a temporal "sequence" (more than one consecutive image). Additionally, the method is not understood to require more than one session, regardless of whether the image(s) are designated pre-therapy or therapy. This simply designates whether the image was acquired before or during one (single) therapy session. The pre- and therapy images are understood to be a part of the same session and therefore the same sequence (as they have also been shown to create a temporal sequence of images of the same patient in a single session). The beam direction data of Schweikard et al. is held to constitute "treatment data" as claimed.

1.2 Claims 24-26, 32, 33, 34, 35, 36, 38, 39, 40, 41, 42, 47, 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Schweikard et al. (US 2004/0092815).

Schweikard et al. disclose a method of performing a medical procedure and corresponding system including providing a plurality of templates, each of which includes image and treatment data and corresponds to a phase of a physiological cycle, as in the abstract, [0021], [0023]. Prior to treatment, CT images of the patient are acquired, with each corresponding to a particular point in the respiratory cycle, as in [0023]. At each point within the respiration cycle, the position of the target is ascertained and this is used to direct the position of the radiation beaming apparatus to continuously focus on the target region during treatment, as in [0028]. During treatment, subsequent anatomical images are acquired for registering or matching with the template images acquired prior to treatment, as in [0024]. From this matching, the location and shape of the target region and phase of the respiratory cycle can be determined. The information regarding the location and shape of the target region is used to direct the radiation beam, with the direction of the beaming apparatus being the treatment data as it is one or more parameters used to control operation of a radiation machine.

A plurality of digitally reconstructed radiographs (DRRs) are computed from the images acquired prior to treatment and each is compared with each live (input) image to determine a match, as in [0023], [0024], [0044]. A moving object (i.e., the target treatment location) is marked for enhanced viewing within each image, as in [0040].

The automated process of comparing images and using the matched image to position the radiation beam entails use of computer readable media and programmed instructions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 11-13, 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalend et al. in view of Takeo (US 6,125,166).

Kalend et al. disclose a method for gating a medical procedure, such as a radiation therapy procedure, in which a sequence of images is acquired, e.g., a simulation image prior to treatment and a series of portal images during treatment, as in col. 1, lines 21-47. A comparison among images is made and the images are matched or aligned with one another by an automatic process making use of fiducials within the image, as in col. 2, lines 19-22 and lines 36-67. The aligned images are displayed as a composite image in which a portal image is superimposed or overlaid with the simulation image or a portal image is overlaid with a preceding portal image to track patient movement during the procedure for driving the positioning assembly or gating the radiation beam, as in col. 5, lines 21-25, col. 4, lines 1-4 and lines 49-52, col. 6, line 61 – col. 7, line 3, col. 9, lines 14-21. A composite image or an alignment (matching) of two images is therefore directly used to turn the radiation beam on or off, as in col. 9, lines 14-21. The method is performed on a series of successive image frames such that multiple matched (composite) images are formed, as in col. 9, lines 14-16.

The method is useful for automatically repositioning the patient during a procedure such that any movement of the patient realigns the radiation beam with the treatment tumor site, so the

motion information derived from the composite image is necessarily effective for controlling the medical procedure in real time. The method is computer controlled and therefore understood to be executed with a processor and a computer readable medium having stored instructions for carrying out the method steps, including acquiring a series of images and determining composite (matched) images useful for controlling a radiation procedure.

Kalend et al. disclose all features of the invention as substantially claimed, as detailed above, including control of a radiation medical procedure based in part on a composite image comprised of a matching of two images, as in col. 9, lines 14-21, but do not specifically address that this composite image is a subtraction image. However, Takeo teaches a method of forming energy subtraction images and discloses using contrast values to determine threshold values (col. 1, lines 50-64 for the subtraction process; also col. 19, lines 11-28 in which a contrast value is used). It would have been obvious to one of ordinary skill in the art at the time of invention to control a radiation therapy procedure based on a composite image that is comprised of a subtraction of two images, as a subtraction image highlights the differences between images and changes between successive image frames are being detected in Kalend et al., as in col. 9, lines 8-21. It would have been obvious to one ordinarily skilled in the art to use a contrast value of the image for reference as taught by Takeo in the method of Kalend et al., as gating a radiation procedure based on successive images enables tracking of patient motion due to breathing, for example, such that radiation is maintained at the target site and discontinued upon detection of movement above a threshold.

Takeo additionally teaches subtraction (composite) images and discloses using contrast values to determine threshold values, as in col. 1, lines 50-64 and col. 19, lines 11-28, in which a

contrast value is used. Examiner posits that a subtraction as disclosed in Takeo is performed on consecutive images in a series. As the designations "first" and "second" are merely names to identify the images of the method being used in the subtraction process, the examiner holds that the consecutive images used in the subtraction in the methods disclosed are identifiable as first and second images in a series. Additionally, it is understood that the methods accommodate uninterrupted image acquisition in which multiple composite images are formed by a process of image subtraction between subsequent images in real time. It is further held, by corollary, that each of the images in each of the sets of composite-subtractions are "first" and "second" with the first being the one that is temporally preceding the second in a consecutive image series.

2.2 Claims 27, 31, 37, 43, 46, 49, 50, 53, 54, 55, 57, 58, 59, 62, 63, 64, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schweikard et al. (US 2004/0092815) in view of Kalend (US 5,784,431).

Schweikard et al. discloses all features of the invention as substantially claimed, as detailed in above section 3, including adjusting the delivery of a radiation beam by controlling operation parameters of a radiation beam by directing the beam based on movement of a target treatment location, but are not particular to turning the radiation beam on or off based on movement of the target; however, in the same field of endeavor, Kalend teaches gating a medical procedure, such as a radiation therapy procedure, by making a comparison among images to track movement during a procedure for driving the positioning assembly of the radiation beam or turning the beam on or off, as in col. 5, lines 21-25, col. 4, lines 1-4 and lines 49-52, col. 6, line 61 – col. 7, line 3, col. 9, lines 14-21. The matching of two images is directly used to turn the

radiation beam on or off, as in col. 9, lines 14-21. It would have been obvious to one ordinarily skilled in the art at the time of invention to include gating and on/off control of the radiation beam in addition to control of beam positioning in order to ensure that tissue beyond the target location is not irradiated in the case of unexpected or excessive patient movement. Kalend additionally teaches forming a composite image by superimposing a pre-therapy image with a live (moving) image.

It is additionally understood that image enhancement is well known within the resolved skill level of the art, as in cases of visualizing a moving target.

2.3 Claims 28, 29, 44, 45, 51 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schweikard et al. (US 2004/0092815) in view of Kalend (US 5,784,431), as applied to claim 43 above, further in view of Florent et al. (US 2005/0002546).

The combination of Schweikard and Kalend includes all features of the invention as substantially claimed, including formation of composite images, but is not specific to image averaging; however, Florent et al. teach averaging of successive images for enhancement of objects within moving images, as in [0022] and the abstract. It would have been obvious to one ordinarily skilled in the art at the time of invention to average images for this same purpose. It additionally would have been obvious to use the averaged image in the comparison of images (subtraction), such that an image with reduced noise is used to determine the position of the target.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amanda Lauritzen/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit
3737